

K905835

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510(k) Summary of Safety and Effectiveness

Submitter: Instrument Makar, Inc. **Date of Summary:** 12/21/95
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Product: Classification Name: Surgical Apparel (21 CFR 878.4040)
Generic Name: Shoe Cover
Trade/Proprietary Name: Fluid Barrier Knee-High Boots

Substantially Equivalent Product:

Depuy.....Sterile View Knee-High Boots

Description:

The Fluid Barrier Boot is manufactured from 6 gauge Poly Vinyl and is available in both knee-high or ankle high boots in small, medium or large sizes. The boots are secured with straps both at the ankle and over the calf on the knee-high boot. The ankle-high boot secures only at the ankle.

Intended Use:

The Fluid Barrier Boot will be used in indications which are the same as that for other shoe covers. Specifically, the Fluid Barrier Boot is intended to be used in the hospital environment to provide protection from all types of fluids in the Operating Room, Central Sterile and in the Emergency Room.

The Fluid Barrier Boot is a disposable product intended for single use only.

Comparison to Substantially Equivalent Product:

The Fluid Barrier Boot has the same intended use as the Sterile View Boot.

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The Fluid Barrier Boots, developed by Instrument Makar, Inc., are substantially equivalent to the Sterile View Knee-High Boots from Depuy (K914702)

These products compare as shown in the table below.

	Instrument Makar, Inc. Fluid Barrier Knee-High Boots	Depuy Sterile View Knee-High Boots
Intended Use	Protect user from fluids in hospital environment	Protect user from fluids in hospital environment
Design	Heat Sealed boot provides protection to just below the knee. It is secured at both the ankle and calf by two vinyl straps manufactured with the same material.	Boot provides protection to just below the knee. It is secured at the ankle by a strap and at the calf by a stretch release top.
Materials	6 gauge Heat Sealed Poly-Vinyl	Tyvek and Vinyl
Physical Safety	Embossed Vinyl to prevent slippage	Skid-resistance surface on sole of boot
Target Population	Hospital Personnel	Hospital Personnel
Biocompatibility	Boot is worn over shoes and scrubs, therefore, will not be in contact with user's skin.	Boot is worn over shoes and scrubs, therefore, will not be in contact with user's skin.
Anatomical Sites	Footwear	Footwear
Additional Notes	Sold Non-Sterile	Sold Non-Sterile

The claim of the fluid barrier name was substantiated by Instrument Makar's 6 gauge Poly-Vinyl passing the "Viral Penetration Test" ASTM Method F1671-95. Thirty-two samples were tested. There were zero failures. All samples 32 samples passed showing no ϕ X174 on the assay plates.